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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,153	02/14/2002	Joseph C. Mase	1417Y P 701	6931

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Stephen R. Auten, Esq.
Wallenstein & Wagner, Ltd.
53rd. Floor
311 S. Wacker Drive
Chicago, IL 60606-6630

EXAMINER	
KOYAMA, KUMIKO C	

ART UNIT	PAPER NUMBER
2876	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,153	MASE ET AL.	
	Examiner	Art Unit	
	Kumiko C. Koyama	2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-25 and 33-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-25 and 33-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *091504*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt of Amendment filed on July 22, 2004.

Information Disclosure Statement

1. The information disclosure statement filed September 15, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because one of the documents in the PTO-1449 (Information Disclosure Statement) fails to identify the required information for a document. The document named "Website pages from the Uniform Code Council, Inc., http://www.uc-council.org, 88 pages (44 sheets), copyrighted 2000" fails to provides author, title, date, pertinent pages etc. And such document contains multiple parts, each having different titles. The Examiner respectfully requests the Applicant to explicitly identify each part or section of the document within the web page. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 103

2. following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 6, 7, 14-17, 22, 33, 37, 39, 43, 59 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada (US 5,237,164) in view of Small et al (US 6,355,024).

Takada teaches a bar code on a card substrate as shown in Fig 4 having a bright portion 28a that reflects light, serving as light-reflecting segments, and dark portions 28b formed by a printing process of black color having a light absorption property, serving as spaces defining light-absorbing segments (col 5 lines 38-55). Takada specifically discloses that the dark portion 28b of the card substrate 28 is left unchanged because it is not needed to reflect incident light (col 5, lines 40-45) and as shown in Fig. 4, the card itself acts as the background or spaces of the bar code image. The bright portion and dark portions define a negative image, as shown in Fig 4. Takada teaches a bar code reader 22 that is used to read out the bar code (col 6 lines 63+). A magnetic strip is positioned over the substrate (Fig 1) and the bar code may be positioned over the magnetic strip (Fig 2). As shown in Fig 3 and Fig 4, the light-reflecting segments are indicia that can be detected by a reader (col 6 lines 63+).

Takada fails to teach a medical container having a bar code and the bar code representing fixed information and variable information, wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price and concentration.

Small teaches a bulk container that contains such fluids as contrast fluid and saline for patients (col 5, lines 24-35 and col 6, lines 40-46), and therefore is a medical container. Small teaches that the bulk container is plastic and has flexible walls as in a plastic bag (col 5, lines 30-35). The bulk container contains an identifier 76 that is a sticker containing a bar code, which contains variety of information such as product name, source, concentration, lot number, expiration date, whether the package had been previously used, etc (col 14, lines 1-7). The lot number, expiration date, concentration are variable information. The product name and source are fixed information.

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Small to the teachings of Takada because negative bar codes as described by Takada has the capability to read out the code from a considerably distant place, and therefore, by integrating such technology to the medical environment, medical information is update by a nurse or other medical staff from a remote location without disturbing the patient or the doctor.

Re claim 15 and 59: Although Takada as modified by Small does not specifically teach a second bar code, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to have a second bar code having an identical format and characteristics regarding the reflection of the bars as the first bar code due to a matter of duplicate creation of another because having two separate barcodes distinctively separates one from another and by such modification it ensures that the fixed information remains unchanged by encoding a lock on the barcode while the other bar code can continuously be updated with new information.

4. Claims 3-5, 34, 40 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small as applied to claims 1 and33 above, and further in view of Dolash (US 4,983,817). The teachings of Takada in view of Small have been discussed above.

Re claim 3, 4 and 34: Takada as modified by Small fail to teach that the indicia is visible to the naked human eye. Takada as modified by Small also fails to teach that the indicia has a color selected from the group consisting of white, red, yellow, orange, gold and silver.

Dolash teaches bar codes with fluoresce orange-red (col 1 lines 55-57).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Dolash to the teachings of Takada as modified by Small so that the bar code can be visible and readable in a more accurate manner when the bar code is on a white background because fluorescent ink provides a more distinctive reflection.

Re claim 5: Takada as modified by Small fails to teach that the indicia is not visible to the naked human eye.

Dolash teaches a bar code that is invisible to the unaided eye (col 10 lines 25-27).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Dolash to the teachings of Takada as modified by Small so that the bar code will not interrupt the visibility of other information that describes the substrate and only the bar code reader can interpret the bar code information.

5. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small as applied to claim 1 above, and further in view of Croft (US 5,893,459). The teachings of Takada as modified by Small have been discussed above.

Small teaches that the bulk container is plastic.

However, Takada as modified by Small does not specifically disclose that the plastic is a thermoplastic polymer or a thermoset polyer.

Croft teaches a pouch like package for packging items, such as individual does pain reliever, including sheets of transparent PVC plastic (col 1, lines 60+). The pouch has a bar code label attached thereto as shown in Fig. 3.

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Croft to the teachings of Takada as modified by Small because PVC plastic is a commonly available material that available at a fairly cheap prices, and therefore, the cost of the product is decrease by the utilization of PVC plastic.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small and Croft as applied to claim 11 above, and further in view of Fujii et al (US 4,311,810). Takada/Small/Croft have been discussed above.

Takada/Small/Croft fail to teach that the polyolefin is produced from an alpha-olefin having from about 2 to about 20 carbons and the alpha-olefin is ethylene or propylene.

Fujii teaches a propylene copolymer consisting of propylene and alpha-olefins of 5-12 carbons (col 2, lines 5-10). Fujii also teaches a pouch made out of the propylene copolymer (col 22, lines 62+).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Fujii to the teachings of Takada/Small/Croft in order provide a clear medical container so that the content of the container can be seen to confirm that the content matches the bar code information.

7. Claims 18-21, 25, 38, 52, 60 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small and McGinty et al (US 6,010,970).

Takada teaches a bar code on a card substrate as shown in Fig 4 having a bright portion 28a that reflects light, serving as light-reflecting segments, and dark portions 28b formed by a printing process of black color having a light absorption property, serving as spaces defining light-absorbing segments (col 5 lines 38-55). The bright portion and dark portions define a negative image, as shown in Fig 4. Takada teaches a bar code reader 22 that is used to read out the bar code (col 6 lines 63+). A magnetic strip is positioned over the substrate (Fig 1) and the bar code may be positioned over the magnetic strip (Fig 2). As shown in Fig 3 and Fig 4, the light-reflecting segments are indicia that can be detected by a reader (col 6 lines 63+).

Takada fails to teach a medical container having a bar code and the bar code representing fixed information and variable information, wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price and concentration.

Small teaches a bulk container that contains such fluids as contrast fluid and saline for patients (col 5, lines 24-35 and col 6, lines 40-46), and therefore is a medical container. Small teaches that the bulk container is plastic and has flexible walls as in a plastic bag (col 5, lines 30-35). The bulk container contains an identifier 76 that is a sticker containing a bar code, which contains variety of information such as product name, source, concentration, lot number, expiration date, whether the package had been previously used, etc (col 14, lines 1-7). The lot number, expiration date, concentration are variable information. The product name and source are fixed information.

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Small to the teachings of Takada because negative bar codes as described by Takada has the capability to read out the code from a considerably distant place, and therefore, by integrating such technology to the medical environment, medical information is update by a nurse or other medical staff from a remote location without disturbing the patient or the doctor.

Takada as modified by Small fails to teach an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

McGinty discloses a bar code readability grade, according to ANSI standard X3.182-1990, of at least 3.0 (Grade B), using Code 39 symbology with a narrow band width of 0.0096 inch (0.0244cm) (col 3, lines 47-52).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of McGinty to the teachings of Takada as modified by Small in order to provide a faster process because a scan grade of A or B shows a low possibility of rescan rate and therefore, the possibility of reading the bar code at a first scan in an accurate manner is high.

Re claim 19: Although Takada as modified by Small does not specifically teach a second bar code, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to have a second bar code having an identical format and characteristics regarding the reflection of the bars as the first bar code due to a matter of duplicate creation of another because having two separate barcodes distinctively separates one from another and by

such modification it ensures that the fixed information remains unchanged by encoding a lock on the barcode while the other bar code can continuously be updated with new information.

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small and Berquist (US 4,884,904).

Takada teaches a bar code on a card substrate as shown in Fig 4 having a bright portion 28a that reflects light, serving as light-reflecting segments, and dark portions 28b formed by a printing process of black color having a light absorption property, serving as spaces defining light-absorbing segments (col 5 lines 38-55). The bright portion and dark portions define a negative image, as shown in Fig 4. Takada teaches a bar code reader 22 that is used to read out the bar code (col 6 lines 63+). A magnetic strip is positioned over the substrate (Fig 1) and the bar code may be positioned over the magnetic strip (Fig 2). As shown in Fig 3 and Fig 4, the light-reflecting segments are indicia that can be detected by a reader (col 6 lines 63+).

Takada fails to teach a medical container having a bar code and the bar code representing fixed information and variable information, wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price and concentration.

Small teaches a bulk container that contains such fluids as contrast fluid and saline for patients (col 5, lines 24-35 and col 6, lines 40-46), and therefore is a medical container. Small teaches that the bulk container is plastic and has flexible walls as in a plastic bag (col 5, lines 30-35). The bulk container contains an identifier 76 that is a sticker containing a bar code, which contains variety of information such as product name, source, concentration, lot number, expiration date, whether the package had been previously used, etc (col 14, lines 1-7). The lot

number, expiration date, concentration are variable information. The product name and source are fixed information.

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Small to the teachings of Takada because negative bar codes as described by Takada has the capability to read out the code from a considerably distant place, and therefore, by integrating such technology to the medical environment, medical information is update by a nurse or other medical staff from a remote location without disturbing the patient or the doctor.

Berquist teaches a bar code printer for printing data on a web of material, the printer being a thermal print head type printer and inputting signal to the printer (col 1 line 9-12, col 4 lines 60-64).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Berquist to the teachings of Takada as modified by Small in order to print the bar code so that the bar code can be generated to store information and identify the item that the bar code is applied to, therefore providing a unique identification to quickly identify and obtain information about the item.

9. Claims 35, 36, 41, 42 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small and Dolash as applied to claim 34, 40, 64 above, and further in view of Inoue et al (US 5,418,357). The teachings of Takada as modified by Small and Dolash have been discussed above.

Takada as modified by Small and Dolash fail to teach that the bar code is two-dimensional symbology and utilizing Code 39.

Inoue teaches a two-dimensional bar code and Code 39 (col 1, lines 17-30).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Inoue to the teachings of Takada as modified by Small and Dolash because two dimensional bar code has the capability of storing more information than a one dimensional barcode, and therefore, it is capable of providing more specific and detailed information regarding the product.

10. Claims 44-50, 53, 57, 58, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small and McGinty as applied to claims 17, 18 and 20 above, and further in view of Atsumi et al (US 5,739,520). The teachings of Takada as modified by Small and McGinty have been discussed above.

Takada as modified by Small and McGinty fail to teach that the bar code has a length of less than or equal to 22 millimters.

Atsumi teaches that the length of the bar code is 20mm (col 1, lines 15-20).

Therefore it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Atsumi to the teachings of Takada as modified by Small and McGinty in order to such that the bar code does not interfere with the visibility of the content when the container is clear.

11. Claims 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small and McGinty and Atsumi as applied to claim 53 above, and further in view of Beavers et al (US 4,939,009). The teachings of Takada/Small/McGinty/Atsumi have been discussed above.

Takada/Small/McGinty/Atsumi fail to teach that the thickness of the pouch is at least 8 mils.

Beavers teaches that the film had a total thickness of 8mils (col 6, lines 67-68).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Beavers to the teachings of Takada/Small/McGinty/Atsumi in order to have a sturdy container that can hold sterile solution for the patient.

12. Claims 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small as applied to claim 64 above, and further in view of McGinty and Atsumi. The teachings of Takada as modified by Small have been discussed above.

Takada as modified by Small fails to teach an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

McGinty discloses a bar code readability grade, according to ANSI standard X3.182-1990, of at least 3.0 (Grade B), using Code 39 symbology with a narrow band width of 0.0096 inch (0.0244cm) (col 3, lines 47-52).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of McGinty to the teachings of Takada as modified by Small in order to provide a faster process because a scan grade of A or B shows a low possibility of rescan rate and therefore, the possibility of reading the bar code at a first scan in an accurate manner is high.

Takada as modified by Small and McGinty fail to teach that the bar code has a length of less than or equal to 22 millimters.

Atsumi teaches that the length of the bar code is 20mm (col 1, lines 15-20).

Therefore it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Atsumi to the teachings of Takada as modified by Small and McGinty in order to such that the bar code does not interfere with the visibility of the content when the container is clear.

13. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small as applied to claim 63 above, and further in view of Ackley (US 5,486,689). The teachings of Takada as modified by Small have been discussed above.

Takada as modified by Small fail to teach the spaces have a maximum reflectance of about twenty-five percent.

Ackley teaches in Fig. 2B that the reflectance percentage of the spaces are within the 25 percent range.

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Ackley to the teachings of Takada as modified by Small in order to distinctively define the differences between space and bars to accurately retrieve the encoded data.

14. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small as applied to claim 6 above, and further in view of Schneider et al (US 4,887,208). The teachings of Takada as modified by Small have been discussed above.

Takada as modified by Small fail to teach that the first period of time is one day.

Schneider teaches that a bar code reader is used to read each of the labels and updates the information so that it can be done on a daily basis (col 4, lines 50-65).

Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Schneider to the teachings of Takada as modified by Small in order to frequently update the information so that the newest information is always available to keep track of the item's whereabouts as well as ensure the patients safety by making sure the content and the expiration date of the item.

Response to Arguments

15. Applicant's arguments filed on July 22, 2004 have been fully considered but they are not persuasive.

Applicant submits that Takada in view of Small fails to teach the limitation of a container "wherein the container defines spaces that separate the light-reflecting segments." However, the Examiner respectfully disagrees. As now described in the rejection above, Takada teaches that the card itself acts as the spaces of the bar code image. Although the dark portion, which is the card, is taught to be formed by a printing process, Takada does not teach nor show that the printed dark portions and the card are separate elements. Rather, Takada teaches in Fig. 4 that the dark portion is actually a part or portion of the card substrate. Therefore, one concludes that the dark portion is included as part of the card. The Examiner submitted Takada teaches a card, but not a container. However, the Examiner has also submitted that the rejections have been made with Takada in view of Small, wherein Small teaches a barcode on a container (which is also a substrate). The Applicant recites that the "container defines spaces," but does not specifically disclose what the container is made out of, or what the container is not made out of. Therefore, the Examiner believes that the prior art reads on the claimed invention.

With respect to Applicant's arguments "a *prima facie* case of obviousness has not been made because only their disclosure provides the requisite motivation for the combination," the Examiner respectfully disagrees. The Examiner has provided that the motivation to combine Takada and Small was the disclosure of Small wherein Small suggests the use of bar code and its reading technology to be implemented in a medical environment such as in medical containers. On the other hand, Takada's invention improves or suggests the use of negative image bar codes because negative image bar codes improves the bar code image reading from a distance location. The Examiner provided combination because it would have been obvious to one in ordinary skill in the art at the time the invention was made to Takada's teachings of negative image bar code to improve distant reading of the bar code with the teachings of Small, in which bar codes are utilized in a medical environment wherein the environment includes patients, devices and medicine that are stationary and require distant reading of the information. Such motivation may not be Applicant's motivation for improvement, however, there is no requirement for the Examiner to provide an identical motivation as the Applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kumiko C. Koyama whose telephone number is 571-272-2394. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on 571-272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kumiko C. Koyama

Kumiko C. Koyama
October 16, 2004

DIANE I. LEE
PRIMARY EXAMINER